

REMARKS

1. Preliminary Remarks

a. Status of the Claims

Claims 21-23, 33-35, and 45-47 were pending. Applicant cancels claim 23 35, and 47. Applicant also amends claims 33-35 and 45-47. Upon entry of the amendments made herein, claims 21, 22, 33, 34, 45, and 46 will be pending and under active consideration in this application.

b. Interview Summary

The undersigned would like to thank the Examiner for the courtesy of the telephone interview of February 5, 2009, wherein the new matter rejection was discussed. The claim amendments made herein are identical to the amendments proposed in the interview. Based on the interview, Applicant believes that the application is in condition for allowance.

2. Patentability Remarks

a. 35 U.S.C. § 112, first paragraph

On pages 2-4 of the Office Action, the Examiner rejects claims 23, 35 and 47 under 35 U.S.C. § 112 for allegedly failing to comply with the written description rejection. The Examiner rejected claim 23 (and dependent vector/probe claims 35 and 47) on the grounds that the specification allegedly does not provide sufficient support for the genus of claimed nucleic acid.

Applicant respectfully disagrees. Nevertheless, in order to expedite allowance of this application and without prejudice to seeking claims of similar scope in a continuing application, Applicant has canceled claims 23, 35, and 47 thereby rendering this rejection moot. In view of the foregoing amendment, Applicant requests withdrawal of the rejection.

b. 35 U.S.C. § 102

(1) Claims 34, 35, 46 and 47

On page 5 of the Office Action, the Examiner rejects claims 34, 35, 46 and 47 under 35 U.S.C. § 102(b) for allegedly being anticipated by WO 93/12234 (Jayasena et al.). The Examiner characterized the claims as drawn to a vector or a probe comprising a nucleic acid that is SEQ ID NO: 5264. The Examiner alleges that the term “probe” does not impart any structural requirements to the nucleic acid sequences in claims 46 and 47. Applicant respectfully disagrees.

As discussed above, claims 35 and 47 have been canceled without prejudice. Amended claims 34 and 46 are now directed to a vector or probe comprising a heterologous sequence,

wherein the heterologous sequence consists of the sequence of the nucleic acid of claim 22 such as SEQ ID NO: 5264. It is important to note that the vector of Jayasena does not comprise a heterologous sequence consisting simply of SEQ ID NO: 5264, but rather comprises a heterologous sequence consisting of the 58-base pair sequence of AAQ44139. Similarly, the probe of Jayasena does not comprise a heterologous sequence consisting of SEQ ID NO: 5264, but rather comprises a heterologous sequence consisting of the 58-base pair sequence of AAQ44139. Accordingly, Applicant submits that scope of the claim is not anticipated by the sequence taught in Jayasena.

With regard to the Examiner's comment that the term "probe" does not impart any structural requirement to the nucleic acid of claim 46, Applicant submits in response that one of ordinary skill would recognize that a nucleic acid, by itself, is not a probe. Probes are typically used to identify a complementary sequence. A nucleic acid, by itself, may bind to a complementary sequences, but one of ordinary skill would recognize that a probe must contain additional structural features to allow one to detect the binding to the complementary sequence. These structural detection features may often be a molecular marker or label, such as ³²P or digoxigenin (DIG). For example, the specification teaches a probe of certain sequences was labeled with DIG and used for detection of miR/hairpin related nucleic acids (See paragraph 155, line 6; paragraph 158, line 4; paragraph 159, lines 1-5, Figures 13B and 13C). The Examiner himself points to Figure 10 of Jayasena, which depicts oligoprobes containing markers (designated "cleaving moiety")

The sequence of Jayasena, by itself, is not a "probe" like the pending claim because it contains only sequences from HIV-1. The claimed probe, however, would be recognized by one of ordinary skill to contain the heterologous sequence that consists of SEQ ID NO: 5265 as well as additional features that would allow detection of binding to a complementary sequence. Accordingly, the claimed probes account for these features, but the sequence of AAQ44139 in Jayasena is not a probe.

In summary, Jayasena fails to teach a vector or probe comprising a heterologous sequence consisting of SEQ ID NO: 5265. In addition, Jayasena does not teach or suggest that a nucleic acid consisting of the AAQ44139 sequence would contain any of the structural features that one of ordinary skill would recognize as being part of a probe. In view of the foregoing amendment and remarks, the Applicant respectfully request that the rejection of claims 34, 35, 46, and 47 under 35 U.S.C. §102(b) for being anticipated by Jayasena has been overcome and should be withdrawn.

(2) Claims 33 and 45

On page 5 and 6 of the Office Action, the Examiner rejects claims 33 and 45 under 35 U.S.C. §102(b) for allegedly being anticipated by WO98/50407 (Ludwig). The Examiner characterized the claims as drawn to a vector or a probe comprising a nucleic acid that is SEQ ID NO: 2194. Again, the Examiner asserts that the term “probe” does not impart any structural requirements to the nucleic acid sequence in claim 45. For the same reasons as discussed for anticipation rejection of claims 34, 35, 46, and 47 discussed above, the Applicant disagrees.

Amended claims 33 and 45 are directed to a vector or probe comprising a heterologous sequence, wherein the heterologous sequence consists of the nucleic acid of claim 21 such as SEQ ID NO: 2194. As with the vector of Jayasena, the vector of Ludwig does not comprise a heterologous sequence consisting of SEQ ID NO: 2194, but rather comprises the 153-base pair heterologous sequence of SEQ ID NO: 8 of Ludwig (hereafter the “AAV81498 sequence”). Similarly, as with the probe of Jayasena, the probe of Ludwig does not comprise a heterologous sequence consisting of SEQ ID NO: 2194, but rather comprises the 139-base pair heterologous sequence of AAV81498.

With regard to the Examiner’s comment that the term “probe” does not impart any structural requirement to the nucleic acid of claim 45, Applicant submits in response the same arguments as discussed above, namely that one of skill would recognize that a nucleic acid, by itself, is not a probe. As with Jayasena, Ludwig fails to teach or suggest particular structural features of probes that would be encompassed by the AAV81498 nucleic acid sequence (*e.g.*, molecular markers).

In summary, Ludwig fails to teach a vector or probe comprising a heterologous sequence consisting of SEQ ID NO: 2194. In addition, Ludwig does not teach or suggest that a nucleic acid consisting of the AAV81498 sequence would contain structural features that one of ordinary skill would recognize as being part of a probe. In view of the foregoing amendment and remarks, the Applicant respectfully request that the rejection of claims 33 and 45 under 35 U.S.C. §102(b) for being anticipated by Ludwig has been overcome and should be withdrawn.

(3) Claims 22, 23, 46, and 47

On page 7 of the Office Action, the Examiner rejects claims 22, 23, 46, and 47 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Appl. Pub. No. 2001/0053519 (Fodor et al.). The Examiner asserts that Fodor teaches methods of making every possible oligonucleotide in the range of 10-25 nucleotides in length. The Applicant respectfully disagrees.

“A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987). The Examiner characterizes Fodor as making every possible oligonucleotide in the range of 10-25 nucleotides in length. Fodor does not teach or suggest the specific nucleotide sequence as set forth in SEQ ID NO: 5264. The anticipation rejection is based on the Examiner’s assertion that SEQ ID NO: 5264 and its probe are species of every possible oligonucleotide in the range of 10-25 nucleotides in length. The disclosure of the genus of every possible oligonucleotide in the range of 10-25 nucleotides in length does not anticipate the sequence of SEQ ID NO: 5264. Accordingly, the Applicant submits that claims 22 and 46 fail to be anticipated by the teachings of Fodor. As discussed above, the rejection as applied to claims 23 and 47 is moot since these claims are canceled without prejudice. In view of the foregoing amendments and remarks, Applicant respectfully submits that the rejection of claims 23 and 47 under 35 U.S.C. §102(b) over Fodor is improper and should be withdrawn.

3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

POLSINELLI SHUGHART PC

Dated: February 9, 2009

By: /Teddy C. Scott, Jr., Ph.D./
Teddy C. Scott, Jr., Ph.D.
Registration No. 53,573
Customer No. 37808

POLSINELLI SHUGHART PC
180 N. Stetson Ave., Suite 4525
Chicago, IL 60601
312.819.1900 (main)
312.602.3955 (E-fax)
312.873.3613 (direct)